



NOBAMED Paul Danz AG

Woundhook cover

REF 324025 (as of LOT 138740)

Product Description, Intended use, Application

Disposable single-layer white covers sewn of medically bleached knitted cotton fabric, **5 cm x 25.5 cm**, packed per 20 pcs, with worked in X-ray thread and with bands. The bands are used to fix the covers at the wound hook. The covers are put on the wound hooks before sterilization, to protect the instruments. The covers may be left on the wound hooks during their use and will thus reduce light reflections caused by the metal due to the operation lamp. At the same time sensitive tissue will be protected against the edges of the wound hooks.

Composition

cotton, x-ray thread made of barium sulfate, PVC, phthalate-free plasticizer

Contraindications

The product should not be used in the case of a known allergy against the material.

Note

Before use on open wounds, the product must be sterilized in accordance with a validated sterilization method (Moist Heat in accordance with DIN EN ISO 17665, Radiation in accordance with DIN EN ISO 11137, or Ethylene Oxide in accordance with DIN EN ISO 11135).

Incident reporting

According to MDR (EU) 2017/745, if serious incidents occur in relation to the device, they must be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Normative and Regulative Requirements, Common Standards

Medical Device according to MDR (EU) 2017/745.

The product does not contain dangerous toxic substances according to REACH.

Packaging

Primary packaging: PE bag

Secondary packaging: carton made of cellulose

Symbols used in labelling

Explanation at www.nobamed.com



Marking on all packaging levels with CE and according to DIN EN ISO 15223-1- and DIN EN ISO 20417

Storage and Transport

Dry and dustfree, protect from sunlight.

Single use device

Reusing a single use medical device can lead to microbiological danger. Reprocessing for reuse can decrease the product's performance significantly.

Disposal

According to locally applicable legal regulations and standards of infection prophylaxis.